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Biotechnology & Life Sciences

Pluristem Therapeutics, Inc. (PSTI)–Buy

PSTI: Initiating Coverage - Buy Rating, $5 PT - Highly Scalable Manufacturing with Low COGS, Allogeneic and Well-Designed Off-the-Shelf Cell Therapy, and Multiple Shots (Indications) on Goal

By leveraging its proprietary 3D cell culture technology, Pluristem Therapeutics is developing allogeneic placenta-derived stem cell therapy for the treatment of severe ischemic, inflammatory, and degenerative diseases. Its lead product, PLX-PAD, has demonstrated safety and encouraging efficacy in Phase 1 trials in critical limb ischemia (CLI). Pluristem has recently engaged in successful discussions with the FDA and EMA and is planning to initiate a comprehensive set of clinical programs in peripheral artery disease (PAD), including a Phase 2 study in intermittent claudication (3Q11), potential pivotal Phase 2/3 study in CLI (4Q11), and a potential pivotal Phase 2/3 study in Buerger's disease (4Q11). The company recently raised $38MM, sufficient capital to support clinical development into 2013. While we acknowledge the risk of developing cell-based therapies in general as well as the early stage PLX-PAD data to date, we believe PSTI represents a favorable risk/reward investment opportunity, given the advantages of allogeneic, off-the-shelf cell therapy, low COGS, and multiple shots on goal in related clinical programs. We are initiating coverage on Pluristem Therapeutics with a BUY rating and a 12-month price target of $5.

- ***3D cell manufacturing: natural environment, efficient production, and low COGS:*** Pluristem's proprietary, patented PluriX 3D bioreactor resembles the natural environment of human bone marrow and allows rapid expansion of cells without using growth factors, thus limiting the differentiation of stem cells and producing genetically stable cells suited for cell therapy. Instead of using thousands of petri-dishes in traditional 2D cell culturing, one 75 liter bioreactor can produce 1,000 doses of cells with 300MM cells/dose, consistent batch-to-batch production, and <5% COGS that compares favorably to other biologics.
- ***PLX advantage: allogeneic, off-the-shelf, yet no need for matching:*** Pluristem's PLacenta eXpanded (PLX) cells are derived from donor placenta (allogeneic). However, both in vitro assays and human studies have shown that PLX cells are immunopriviliged, and there is no need for histocompatibility matching. PLX cells are stored in liquid nitrogen, ready for use, and stable for up to 9 months. The company optimizes the PLX cells for each proposed indication.
- ***Clinical program: multiple shots on goal with lead indication targeting high unmet medical need in CLI.*** Its lead product, PLX-PAD, targets CLI and is associated with >100,000 amputations per year, representing a >$500MM opportunity for PLX cells in this indication alone. We are encouraged by the data to date and expect Phase 3 data in CLI in late 2014/early 2015. In addition, by the end of 2013, we expect significant information to be available from the CLI trial as well as the IC and Buerger's disease programs.

Coverage Initiation

Market Data	
Price (04/01/11)	$2.58
12-Month Price Target	$5.00
52-Week range	$4.20-1.01
Shares Out. (MM)	41.3
Market cap (MM)	$106.5
Avg. daily volume (000)	677.2
Financial Data	
Total Debt/Cap.	7.3%
Price/LTM Rev.	nm
Tangible BVPS	$0.24
Net Cash Per Share	$0.17

Pluristem is a biopharmaceutical company focused on research, development, and commercialization of allogeneic stem cell therapy by leveraging its proprietary 3D cell culture technology. Its lead product PLX-PAD has demonstrated encouraging efficacy in CLI and will soon enter into pivotal Phase 2/3 studies in CLI and Buerger's disease.

NEWSWORTHY EVENTS EXPECTED WITHIN THE NEXT 3-6 MONTHS

- Report updated data from Phase 1 trials of PLX-PAD in CLI (2Q11)
- Initiate a Phase 2 trial of PLX-PAD in intermittent claudication (3Q11)
- Initiate Phase 2 trials of PLX in muscle injuries in both the EU and US (3Q11)
- Initiate a Phase 2/3 trial of PLX-PAD in Buerger's disease (4Q11)
- Initiate a Phase 2/3 trial of PLX-PAD in CLI patients (4Q11)

Disclosures applicable to this security: B, C, D, G, J.
Disclosure explanation on the inside back cover of this report.

EXECUTIVE SUMMARY

Technology Platform—3D Cell Culture, Consistent Production, Low Cost of Goods

We are initiating coverage on Pluristem Therapeutics with a BUY rating and a 12-month price target of $5. Pluristem Therapeutics' proprietary, patented three-dimensional (3D) bioreactor is designed to mimic the structure and function of the natural environment of human bone marrow. Compared to the 2D cell culture methods, PluriX 3D bioreactor has several advantages, including:

1) Simulation of natural environment–Traditional 2D cell culture usually leads to changes in gene expression and morphology in the cultured cells as compared to cells in the natural environment. PluriX 3D bioreactor allows cells to grow and reproduce in a similar way to living organs.

2) Stability and consistency–Unlike 2D cell culture where thousands of petri dishes are used and it is difficult to control the variability between petri dishes, PluriX 3D bioreactor provides easier control of the culture environment and produces more stable and consistent quality of cells from batch to batch.

3) Efficient production with low cost–Pluristem used a 1 liter bioreactor for Phase 1 trials and a 5 liter bioreactor for Phase 2/3 trials and will move to 75 liter bioreactor for commercialization. It is estimated that the total cell production of one 75 liter bioreactor is greater than the production of 20,000 TCF175 petri dishes, a significant saving in human labor, culture material, and facility space. With the PuriX 3D bioreactor, the cost of production may be as low as $1 per million cells.

Pluristem has established a simple four-step manufacturing process to derive its PLacental eXpanded (PLX) cells from a donor placenta, with an in-process control (IPC) based on the FDA guidelines for each single step. PLX cells are manufactured and released under a strict quality control program that includes IPC testing and product-release specifications. When PLX cells are stored in liquid nitrogen, stability testing is performed monthly to ensure the quality of the cells, including test for sterility, viability, and potency.

PLX Advantage—Off-the Shelf, Allogeneic, Yet No Need for Matching

The sources of Pluristem's PLacental eXpanded (PLX) cells are donated (allogeneic) placentas, which are easily accessible, non-controversial, and rich in cells. The PLX cells are cyropreserved in 5% DMSO in liquid nitrogen, ready for use, and are stable for up to 9 months. Unlike MSCs derived from bone marrow, which is limited by the donor availability and may require 50-60 population doubling to achieve sufficient numbers of therapeutic cells, Pluristem is able to produce 10,000 doses of PLX cells with 300MM cells for each dose, while controlling the cell population to no more than 20 doublings. Studies found that MSCs may become genetically unstable and may start to degenerate after 25-40 doublings in vitro.

The PLX cells have an almost identical surface marker profile to MSC, but do not differentiate, thus reducing the risk of tumorgenecity. **PLX cells are shown to be immunoprivileged**, due possibly to their low immunogenicity profile. PLX expresses low levels of MHC class I antigens and are negative for MHC class II antigens and do not exhibit co-stimulatory molecules such as CD40, CD80, and CD 86. **PLX are also shown to display immunosuppressive characteristics by in vitro assays**. PLX cells were shown to decrease lymphoytes proliferation in a dose-dependent manner. In addition, PLX cells are able to decrease the secretion of pro-inflammatory cytokines secreted by activated T cells and secrete anti-inflammatory cytokines. Clinical trials in human found that none of the patients injected with single injections or repetitively challenged with PLX cells developed HLA antibodies against the injected cells. Injection of PLX also caused a trend of reduction in HLA-DR expression on CD14+ blood cells. **The immunopriviledged and immunosuppressive characteristic of PLX cells allow the cells to be used allogeneically without the need for matching. In addition, Pluristem is also able to directionally induce the PLX cells to secrete different cytokines for different therapeutic purposes, thus allowing for optimization in vascular disease, central nervous system disease, and inflammatory conditions.**

Clinical Programs—Multiple Shots on Goal

PLX-PAD for Peripheral Artery Disease

Pluristem's lead product, PLX-PAD, has been developed for the treatment of the limb ischemia from Peripheral Artery Disease (PAD), a disease condition that affects 8-10MM people in the U.S. with ~$14B in treatment associated cost. The company has conducted two Phase 1 trials of PLX-PAD in critical limb ischemia (CLI) that demonstrated the safety and encouraging efficacy of PLX-PAD in CLI patients. **The company plans to initiate a Phase 2/3 study in CLI patients under a joint protocol with FDA and EMA in 4Q11 and a Phase 2 trial in patients with intermittent claudication (IC) in 3Q11 to support the registration in CLI. In addition, Pluristem plans to initiate a Phase 2/3 study in Buerger's disease in 4Q11, an orphan indication that may provide a fast path to the market.**

Ongoing Phase 1 Trials in CLI

Interim results from the two ongoing Phase 1 trials demonstrated that PLX-PAD cells may be safely administered with no significant unfavorable effects. 21 of the 27 treated patients completed three-month follow up. None of the patients developed an anti-HLA antibody response, and no specific anti-PLX HLA class-I or class-II antibodies were detected, even for the patients treated twice with the PLX cells derived from the same placenta. PLX-PAD treatment significantly improved blood flow from baseline for intermediate dose ($p=0.033$), significantly reduced pain score from baseline ($p=0.009$), and significantly improved patients' quality of life ($p<0.001$). Importantly, **only 1/21 patients (4.7%) had a major amputation at 3 months, which compared favorably to the results for the control group in other recently completed clinical trials (12-24% amputation rates).** Updated data from all 27 patients are expected in April 2011.

Planned Phase 2/3 Trial in CLI

Pluristem is expected to initiate a RCT Phase 2/3 study in CLI in 4Q11, under a joint FDA-EMA protocol. The Phase 2/3 trial is expected to enroll 450 patients with Fontaine class III-IV or Rutherford category 4-5 PAD patients. Patients will be randomized 1:1 to receive either PLX-PAD or placebo and each patient will receive two treatments, one at day 0 and one at day 120. PLX-cells will be injected intramuscularly to 30 sites, with 300 million cells for each treatment. **The primary endpoint is amputation-free survival (major amputation or death) rate at 12 months from initiation of the treatment.** The trial is 90% powered to show a 50% reduction, or 80% powered to show a 35% reduction in amputation free survival rate. In addition, an interim analysis is also planned after reaching 80 events, with a potential to stop the trial early due to futility or significant efficacy. **We expect 18 months for trial enrollment and 12-month follow up, with interim look expected in 2013 and final data expected in late 2014/early 2015.**

Planned Phase 2 in IC

Pluristem expects to initiate a RCT Phase 2 study in patients with IC in 3Q11. The trial is expected to enroll 135 patients with IC, randomized 1:1:1 to each of three arms: placebo, low dose PLX-APD (150 million cells), or high dose PLX-PAD (300 million cells). Each patient will receive two treatments, one at day 0 and one at day 120. **The primary endpoint is percentage of patients with > 50% improvement in 6-minute walking distance at 12 months as compared to baseline.** This trial targets patients with Fontaine class IIb or Rutherford class 2 and 3 PAD, and will support the CLI registration. The company plans to use measures to reduce inter- and intra-patient variability, by enrolling patients with at least 2 of 3 treadmill tests within a pre-specified standard deviation and baseline 6-minute walking distance of ~500 meters. The company expects a 50% improvement with PLX-PAD therapy. **We expect 6 months enrollment and 12 months follow up, with data expected in 2013.**

Planned Phase 2/3 in Buerger's Disease

Pluristem has submitted an orphan drug application for PLX-PAD for the treatment of Buerger's disease, and plans to initiate a Phase 2/3 pivotal trial in 4Q11. Since amputation is not a common outcome in Buerger's disease, the company proposed pain reduction and improvement in walking distance as the primary endpoint for the trial.

PLX in Other Indications

In addition to PAD, Pluristem has conducted a variety of pre-clinical studies and generated early evidence of effect in multiple indications, including muscle injury, wound healing, and neuropathic and inflammatory pain as well as ischemic stroke, inflammatory bowel disease, and CNS disorders.

PLX for muscle injury: Pre-clinical data demonstrated that PLX cells treatment following muscle injury resulted in significant improvement in the recovery of muscle function when compared to the control group. Pluristem has started discussions with the Paul Ehrlich Institute (PEI) of Germany regarding a clinical development plan for the usage of PLX cells as an adjuvant therapy for the recovery of muscle function following hip replacement surgery. In addition, the company plans to discuss with the FDA regarding a clinical development plan for PLX cells for the treatment of sports injury, including hamstring injury and tendon/ligament tears. **The company expects to initiate an EU Phase 1/2 study in patients with hip replacement, and a U.S. Phase 1/2 study in patients with sports injury in 3Q11.**

PLX for wound healing: In March 2011, Pluristem formed a partnership with the New York University Medical Center to conduct pre-clinical studies to evaluate PLX cells for the treatment of diabetic foot ulcers (DFU). **We believe that PLX cells may have potential in treating DFU by stimulating angiogenesis and promoting tissue regeneration. The company plans to initiate a Phase 2 study in 2012, if the preclinical data are positive.**

PLX for neuropathic pain: Pre-clinical studies demonstrated that PLX cells may be effective in treating both neuropathic and inflammatory nerve pain, potentially by reducing the sensitivity to the thermal and mechanical stimuli in both models in a dose dependent manner. Pluristem plans to move forward to study PLX cells in the treatment of neuropathic pain associated with diabetes and chemotherapy.

Financial and Valuation Analyses

We are initiating coverage of Pluristem with a Buy rating and a 12-month price target of $5. We derived our price target for Pluristem based on valuation of comparable companies. While we believe that PLX cells may have a >$500MM revenue potential for the CLI condition alone, we believe it is premature to project revenues or earnings for the company at this stage, as the only data available are from Phase 1 trials, and there is uncertainty regarding the clinical trials, regulatory requirement, and potential issues surrounding scale-up of manufacturing and reimbursement. We believe a valuation model based on comparable companies is more appropriate than a revenue or EPS model. We chose our comparable companies for Pluristem based on: 1) compounds already in or soon to enter Phase 3 development; 2) encouraging Phase 1/2 results; 3) unmet medical need; and 4) a technology platform that can be leveraged for further product development. These companies included ArQule Inc. (ARQL, BUY), Athersys (ATHX, NR), Celldex (CLDX, BUY), Cytori (CYTX, NR), Sangoma (SGMO, NR), Stem Cell (STEM, NR), and Vical (VICL, NR). We also note that recently Cephalon paid $130MM upfront and another $220MM in equity investment to Mesoblast to acquire worldwide rights to specific Mesoblast's stem cell products, with additional milestone payments that may reach $1.7 billion.

We believe Pluristem stock is trading at substantial discount relative to its peers. In the near term, we believe the trial initiations, data updates from the ongoing clinical trials may drive the stock higher. In the long term, we believe the results from the clinical programs in PAD and muscle injury, as well as the PLX technology platform, will drive the long-term growth of the company.

As of March 31, 2011, the company had pro forma cash of ~$45MM, including ~$38MM net proceeds from the sale of common stocks and warrants in February 2011. The company estimates that it may cost ~$15MM to conduct the pivotal Phase 2/3 trial in CLI, ~$5M to conduct the Phase 2 trial in IC, and ~$1.5MM to conduct the Phase 2/3 trial Buerger's disease. **With an expected net cash burn of ~$4MM for FY2011, we believe the company has sufficient cash to support operations and clinical programs through 2013.**

COMPANY HIGHLIGHTS

Pluristem Therapeutics, based in Haifa, Israel, is a biopharmaceutical company focusing on research, development and commercialization of allogeneic stem cell therapy products for the treatment of severe ischemic, inflammatory, and degenerative disorders. **The company is developing a pipeline of products derived from donor placenta and expanded by using the company's proprietary 3D bioreactor. Pluristem's first product, PLX-PAD (for the treatment of Peripheral Artery Disease), has demonstrated safety and encouraging efficacy in patients with critical limb ischemia (CLI) in two Phase 1 studies.** The company plans to initiate a Phase 2/3 trial in CLI under a joint FDA-EMA protocol in 4Q11, and a Phase 2 trial in intermittent claudication (IC) in 3Q11, as well as a Phase 2/3 trial in Buerger's disease in 4Q11. In addition, the company expects to initiate Phase 1/2 studies to evaluate PLX cells in muscle injury in 3Q11.

Figure 1: Pluristem's Pipeline

Product	Indication	Status	Comments	Partnership
PLX-PAD	CLI	Phase 2/3 (planned)	Expected to start 4Q11, RCT, n=450, including patients with Fontaine class III-IV or Rutherford class 4-5. 1:1 randomization to either placebo or PLX-APD (300MM cells). Two treatments separated by 4 months. Primary endpoint amputation free survival at 12 month. 90% powered to detect 50% reduction or 80% powered to detect 35% reduction in AFS. Trial design agreed by the FDA and EMA. Expect 18 months enrollment, 1-year follow-up. Interim data expected 2013, and final data in late 2014/early 2015.	Unpartnered
	IC	Phase 2 (planned)	Expected to start 3Q11, RCT, n=135, including patients with Fontaine class IIb or Rutherford class 2-3. Three arms: control, low dose PLX-PAD (150MM cells), or high dose PLX-PAD (300MM cells). Two treatments separated by 4 months. Primary endpoint improvement of 6-minute walking distance at 12 month. Powered to detect 50% improvement. Data expected 2013.	
	Buerger's Disease	Phase 2/3 (planned)	Expected to start 4Q11. Proposed design: primary endpoint pain reduction and improvement in walking distance. Orphan drug application submitted.	
	CLI	Phase 1	Two trials initiated in 2009, one in the U.S. (n=12) and one in the EU (n=15). Interim results reported in September 2010 from 21 patients who completed three-month follow-up. PLX-PAD treatment resulted in significantly improved blood flow, tissue oxygenation, quality of life for the patients, as well as significantly reduced pain. Only one major amputation at 3 month. The data also showed that PLX-PAD is safe, and no immune response was detected. Updated data expected 2Q11	
PLX-Muscle Injury	Muscle Injury	Phase 1/2 (planned)	Phase 1/2 studies expected to start 3Q11. EU trial focusing on patients with hip replacement, U.S. trial focusing on sports injury. Three months follow-up, data expected 1H12. Preclinical data demonstrating that PLX cells, administrated locally immediately or seven days after injury, resulted in significant improvement of muscle function in animal models.	
PLX-Wound Healing	Wound Healing	Preclinical	Pre-clinical studies ongoing in collaboration with NYU Medical Center, potential to bridge a Phase 2 study in human in 2012.	
PLX-Neuropathic Pain	Neuropathic pain	Preclinical	Preclinical studies showed that PLX cells significantly reduced the sensitivity to the thermal and mechanical stimuli in both neuropathic pain and inflammatory nerve pain animal models.	

Source: Company reports, Needham & Company, LLC.

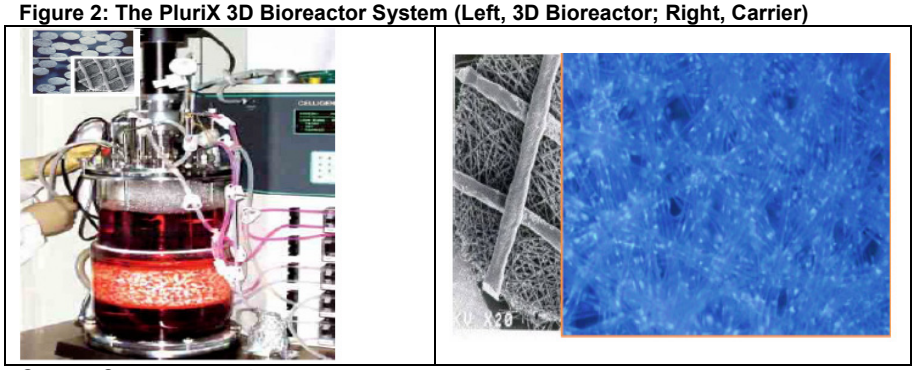
CORE TECHNOLOGY

PluriX 3D Bioreactor

Pluristem's proprietary, patented three-dimensional (3D) bioreactor is designed to mimic the structure and function of the natural environment of human bone marrow. Compared to the traditional two-dimensional (2D) cell culture where cells are cultured in an unnatural flat surface, PluriX 3D bioreactor has several advantages, including:

1) Simulation of natural environment: Traditional 2D cell culture usually leads to changes in gene expression and morphology in the cultured cells as compared to cells in the natural environment. PluriX 3D bioreactor allows cells to grow and reproduce in a similar way to living organs, thus producing cells that behave more similarly to the cells in human body.
2) Stability and consistency: Unlike 2D cell culture where thousands of petri dishes are used and it is difficult to control the variability between petri dishes, PluriX 3D bioreactor provides easier control of the culture environment and produces more stable and consistent quality of cells from batch to batch.
3) Efficient production with low cost: Pluristem used a 1 liter bioreactor for Phase 1 trials and a 5 liter bioreactor for Phase 2/3 trials and will move to 75 liter bioreactor for commercialization with a simple linear scale up. Pluristem has overcome the challenges in 3D cell culture, including design and choice of material of the scaffold to support the cells, the actual culturing methods, and control of the nutrient and waste exchange. It is estimated that the total cell production of one 75 liter bioreactor is greater than the production of 20,000 TCF175 petri dishes, a significant saving in human labor, culture material, and facility space. With the PuriX 3D bioreactor, the cost of production may be as low as $1 per million cells.

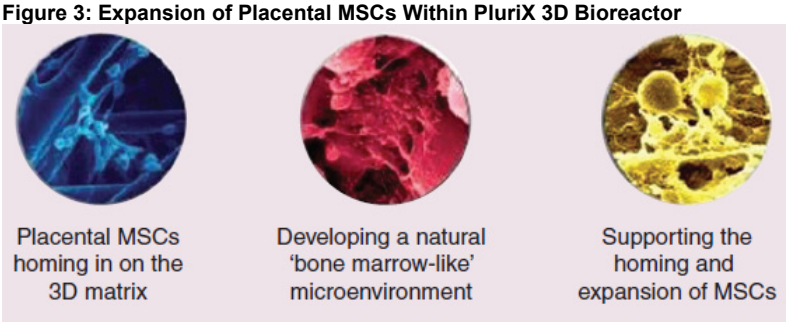
Figure 2: The PluriX 3D Bioreactor System (Left, 3D Bioreactor; Right, Carrier)



Source: Company reports.

The PluriX 3D bioreactor does not use growth factors or other exogenous materials, thus it does not induce the differentiation of stem cells. It is found that mesenchymal stem cells can home to the polystyrene rungs of the nonwoven fibrous matrix within the bioreactor and expand to as much as $65x10^6$ cells/g of matrix. One 75 liter bioreactor may be loaded with 5,000 grams matrix and produce 1,000 doses worthy of cells with 300 million cells per dose. The PluriX 3D bioreactor was originally developed for sale to other biotechnology companies and the research community. In 2006, the company shifted its business strategy to using the 3D bioreactor to develop and commercialize cell therapy products.

Figure 3: Expansion of Placental MSCs Within PluriX 3D Bioreactor



Source: Company reports.

PLX Manufacturing Process

Pluristem coined the term PLX for its Placental eXpanded cells, which are allogeneic, off-the-shelf, mesenchymal stem cells (MSC) like adherent stromal cells for therapeutic purpose. The production process of PLX cells is performed under GMP regulations and involves the following major steps:

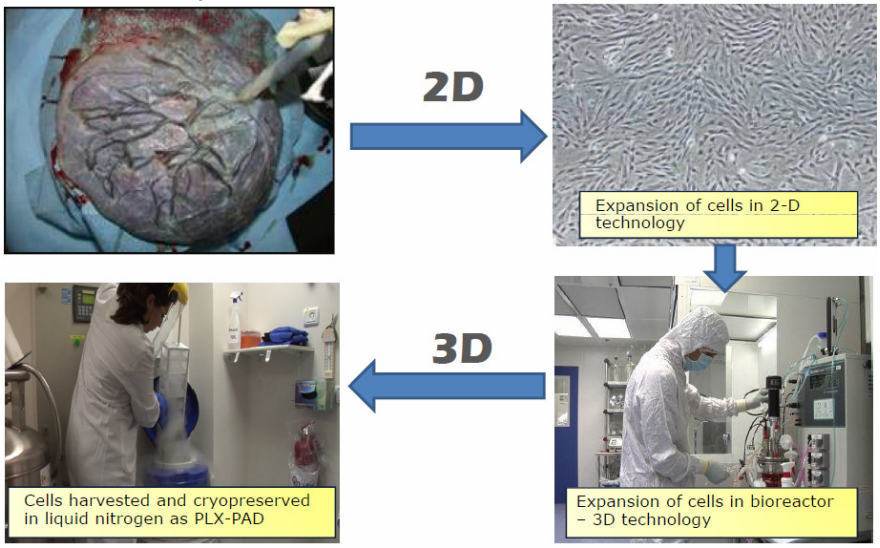
1) Placental qualification and processing: Placentas are obtained from a consented donor mothers following scheduled Caesarean sections. All placenta donors are screened and tested to ensure healthy donors. After delivered to Pluristem, placentas are tested and released for use by quality control and quality assurance. Unqualified placentas are discarded. Within 4 hours following the Caesarean section, placentas are processed and incubated with 0.1% collagenase for three hours. The digested tissue is roughly filtered, washed, and seeded in 2D-medium flasks.

2) 2D culturing: after 24 hour incubation, adherent stromal cells will adhere to the flask surface, and the rest of the tissue debris is washed out with PBS buffer. The cells are then harvested and stored in liquid nitrogen as 2-D cell stock (2DCS). The 2DCS is considered an in-process intermediated product and tested for sterility, mycoplasma, immunophenotype, and viability.

3) 3D expansion: 2DCS that meets the release specifications is then seeded onto carriers in PluriX 3D bioreactor for further expansion. After 1-2 weeks of growth in the bioreactors, the cells can be expanded to $65x10^6$ cells/g matrix, but controlled to limit expansion to no more than 20 doublings. Pluristem estimates that one 75 liter bioreactor is sufficient to generate 1000 doses of PLX cells with 300 MM cells per dose.

4) PLX storage: the expanded cells are then harvested, tested again for phenotypic and karyotupic changes, and cryopreserved in liquid nitrogen for future usage. According to the company, cells are stored under 5% DMSO which can keep the cells stable for up to 9 months.

Figure 4: PLX Production Process Involves Four Simple Steps with Strict Quality Control at Each Step



Source: Company reports.

Pluristem established an in-process control (IPC) based on the FDA guidelines for the entire manufacturing process. PLX cells are manufactured and released under a strict quality control program that includes IPC testing and product-release specifications. Specifically, the immunophenotype characterization includes testing for MSC-positive markers CD73, CD29, and CD105, with specification set as ≥90%, and for the absence of markers CD34, CD45, CD19, CD14, and HLA-DR, with specification set as ≤3%. When PLX cells are stored in liquid nitrogen, stability testing is performed monthly to ensure the quality of the cells, including test for sterility, viability, and potency. Cells are tested for the ability to secrete cytokines: cells are then optimized for the given target medical condition, including vascular disease, CNS disease, muscle disease, and cardiovascular disease, with the ability to select cells with varying cytokine secretion profiles.

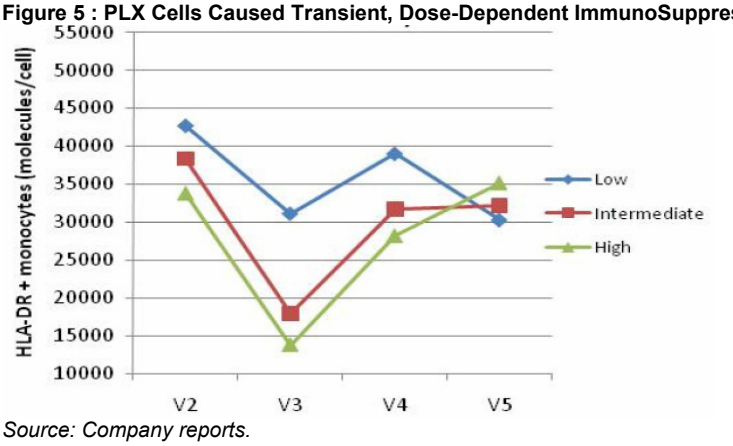
PLX Advantage

Pluristem's therapeutic cells PLX are derived from donor placentas, which are easily accessible, less controversial than other stem cell origins, and rich in cells. By using its proprietary manufacturing platform, Pluristem is able to produce 10,000 doses of PLX cells with 300MM cells/dose from one placenta through the expansion of the cell population with no more than 20 doublings. We believe this provide a significant advantage over other cell-based therapies, such as bone marrow derived MSCs, which is limited by the donor availability and may require 50-60 population doublings to achieve sufficient numbers of therapeutic cells. Studies have found that MSCs may be expanded in vitro for only a limited time period, usually 8-15 passages or 25-40 population doublings. Then the cells slow down in proliferation and begin to degenerate. Molecular profile and function of the cells have shown that cells may become unstable and lose their differential potential after 25 cell doublings. Therefore, **the ability to control the doubling times is critical for maintaining the stability of the cells as well as potentially providing a consistent therapeutic effect from the small-scale Phase 1/2 clinical trials to date to the planned, large-scale Phase 3 trials.**

Pluristem describes PLX cells as adherent stromal cells (ASC) that have surface marker profiles similar to MSCs, with high expression of MSC markers and low expression of hematopoietic, dendritic, and endothelial markers. PLX cells have high expression of typical MSC surface markers, including CD105, CD73, CD90, and CD29, but markers for hematopoietic (CD45 and CD34), endothelial (CD31) or dentritic cells (CD80 and CD86) was detected only at very low levels. **PLX cells are shown to be *immunoprivileged***, due possibly to their low immunogenicity profile. PLX expresses low levels of MHC class I antigens, are negative for MHC class II antigens, and do not exhibit co-stimulatory molecules such as CD40, CD80, and CD 86. Lack of MHC Class II molecules is necessary to escape immune surveillance, and low levels of MHC class I protect the cells from natural killer cell mediated cytotoxicity. **PLX cells are also shown to display *immunosuppressive* characteristics by in vitro assays**. When PLX cells were presented to lymphocytes that were stimulated by antigens, lymphoyte proliferation was suppressed in a dose-dependent manner. In addition, in vitro assay also showed that PLX cells are able to decrease the secretion of pro-inflammatory cytokines secreted by activated T cells, including TNFα, TNFβ, and INFγ. PLX cells also secrete anti-inflammatory cytokines, including IL-10 and TGFβ, as well as IDO upon INFγ stimulation, a cytokine that mediates immunosuppression of tryptophan.

The immunoprivileged and immnosuppressive characteristics of PLX cells have been confirmed also in clinical trials. In the Phase 1 trials in CLI, none of the patients injected with single injections or repetitively challenged with PLX develop HLA antibodies against the injected cells. Injection of PLX caused a trend of reduction in HLA-DR expression on CD14+ blood cells one week following PLX application. This reduction was transient and remained in all patients at levels that indicate no immunosuppression in injected patients.

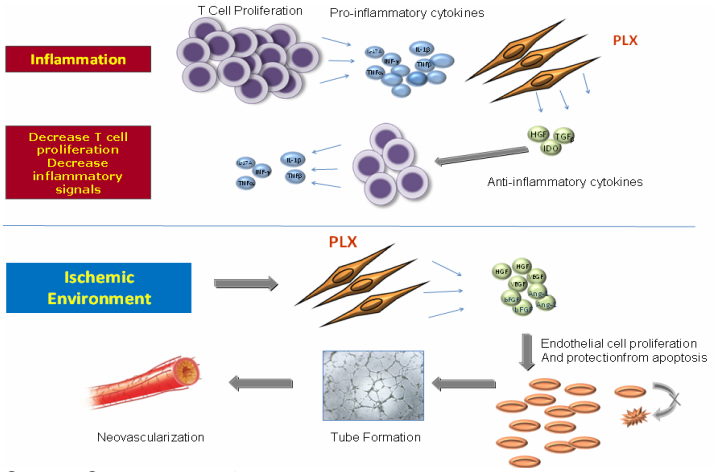
Figure 5 : PLX Cells Caused Transient, Dose-Dependent ImmunoSuppression



Source: Company reports.

While PLX cells have similar surface marker profile as MSCs, PLX cells *lack the ability to differentiate.* And unlike embryonic stem cells, PLX cells *lack the ability to engraft*, thus decreasing the risk of tumorgenicity. While the exact mechanism of action is not totally understood, Pluristem believes that the PLX cells function as a factory of cytokines and/or other immune modulators that modify the inflammatory environment and promote the growth of endothelial cells and regeneration of damaged tissues. By selection of placenta and modification of the culturing conditions, Pluristem is able to produce PLX cells that secret different cytokines, suited for different therapeutic purpose.

Figure 6: Mechanism of Action of PLX Cells



Source: Company reports

CLINICAL PROGRAMS

PLX-PAD for Peripheral Artery Disease

Pluristem's lead product, PLX-PAD, has been developed as an allogeneic cell therapy product for the treatment of the limb ischemia from Peripheral Artery Disease (PAD). The company has conducted two Phase 1 trials of PLX-PAD in critical limb ischemia (CLI) that demonstrated the safety and encouraging efficacy of PLX-PAD in CLI patients. **The company plans to initiate a Phase 2/3 study in CLI patients under a joint protocol with FDA and EMA in 4Q11 and a Phase 2 trial in patients with intermittent claudication (IC) in 3Q11 to support the registration in CLI. In addition, Pluristem plans to initiate a Phase 2/3 study in Buerger's disease in 4Q11, an orphan indication that may provide a fast path to the market. By the end of 2013, data readouts for all three trials (IC and Buerger – final data, CLI – interim data) may be available to determine the registration and commercialization strategy going forward.**

PAD and CLI Background

Peripheral arterial disease (PAD) is a disorder of the peripheral arteries, where plaque builds up that obstruct the blood flow. PAD affects ~20 million people worldwide and is associated with 3-6-fold increase of risk for cardiovascular morbidity and death compared to people without PAD. While many people with PAD have mild or no symptoms, some people may have pain while walking (intermittent claudication, or IC). The severity of IC varies from mild discomfort to debilitating pain that may make it difficult for patients to walk or conduct other type of physical activity. CLI is the most advanced form of lower extremity PAD, and the estimates of the disease burden vary. **A conservative estimate includes ~1MM patients in the U.S. and ~2-3MM patients worldwide.** CLI occurs when arterial lesions obstruct blood flow and perfusion pressure to a point where blood levels are insufficient to satisfy the needs of the limb. Patients experience chronic ischemic rest pain, ischemic skin lesions, such as ulcers and gangrene, or tissue loss. Physical examination demonstrates skin discoloration, temperature changes, absence of peripheral pulses, muscle or subcutaneous tissue and skin atrophy, dry fissures, and petechial bleeding.

There are several ways of assessing the severity of PAD. One commonly used parameter is the ankle-brachial index (ABI), the ratio of the systolic pressure at the dorsalis pedis or posterior tibial artery in the leg divided by the systolic pressure at the brachial artery in the arm. Patients with claudication typically have an ABI of 0.5-0.8, while patients with critical limb ischemia usually have an ABI of 0.4 or less. PAD can be classified based on the symptoms and severity. There are two commonly used classifications: **Fontaine classification is more commonly used in Europe, and Rutherford classification is more commonly used in the U.S.**

Figure 7: Classification of Peripheral Arterial Disease, Fontaine & Rutherford Scales

Fontaine Classification		Rutherford Classification	
Class	Symptom	Class	symptoms
I	Asymptomatic	0	Asymptomatic
IIa	Mild claudication	1	Mild claudication
IIb	Moderate to severe claudication	2	Moderate claudication
		3	Severe claudication
III	Ischemic rest pain	4	Ischemic rest pain
IV	Ulceration or gangrene	5	Minor tissue loss
		6	Major tissue loss

Source: American Heart Association, Medical literature, Needham & Company, LLC.

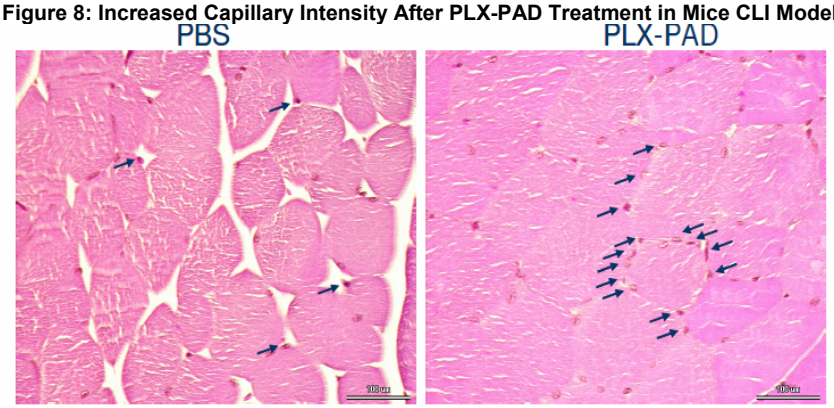
The goals of treatment of CLI are to relieve ischemic pain, heal ischemic ulcers, prevent limb loss, improve patient function and quality of life, and prolong survival. **Current treatment options include revascularization, supportive pharmacological treatment, and amputation.** It is estimated that 50% of newly diagnosed CLI patients are suitable for revascularization, 25% will require amputation, and 25% need some other form of medical treatments if they are not operable or amputation is not immediately required. For patients who are able to tolerate procedures, revascularization, including open surgery bypass and endovascular treatment, offers the best opportunity for limb salvage. Endovascular treatment is consider safe and effective, and is the treatment of choice for patients with less advanced occlusive lesions. The recommended endovascular techniques include balloon angioplasty (PTA), PTA and stent, and subintimal balloon angioplasty. Open surgical bypass procedure is the treatment of choice for patients with advanced occlusive lesions. However, revascularization is not curative for every patient. Of the patients who underwent revascularization, 27% needed one revision and 12% needed multiple revisions. 33% of patients who had a revision due to thrombosis needed an amputation, while 2% of patients that had a revision due to stenosis needed an amputation. For patients who are not candidates for revascularization or failed revascularization, pharmacological treatment can be considered as a possible treatment option. Pharmacological interventions may help control pain and infection in the ischemic leg, prevention of progression of systemic atherosclerosis, and optimization of cardiac and respiratory function. However, no pharmacological treatment has demonstrated clear efficacy in reversing the arterial occlusive lesions, and has no impact on long-term health benefit for the patients.

Therefore, most patients who are not candidates for revascularization may end up with amputation within 6 months. Amputation is indicated for patients who have extensive tissue necrosis, refractory ischemic rest pain, life-threatening infection, or a very limited life expectancy due to co-morbidities. While amputation may offer a quick return to an acceptable level of quality of life, **there is significant surgical risk and complications associated with amputation, and long-term prognosis is very poor: ~40% of patients die within 2 years of the first major amputation, and up to 70% of patients die within 4 years.** The average cost for amputation alone is ~$40,000, and the cost of a prosthesis ranges from ~$25,000 to $75,000. **The average reimbursement cost for a CLI patient with gangrene is ~$66,000 (ICD-9 code 440.24).**

Preclinical Proof of Concept Data for PLX-PAD

Pluristem has conducted proof of concept studies in animal models to assess the potential of PLX-PAD as a therapy for CLI. A widely used CLI model, the Balb/c mouse hind limb ischemia model was used, and a total of $1x10^6$ cells were injected intramuscularly, with the control group injected with saline. Results showed that PLX-PAD significantly improved the blood flow (p=0.0008), capillary density (p=0.021), oxidative stress (p=0.034), and endothelial damage (p=0.004), as well as increased limb function, as compared to control vehicle. Post-mortem histological evaluation showed a statistically significant increase in new capillaries in PLX-PAD treated limbs as compared with controls (p=0.021), demonstrating that PLX-PAD have the potential to promote angiogenesis.

Figure 8: Increased Capillary Intensity After PLX-PAD Treatment in Mice CLI Model.



Source: Company reports.

Phase 1 Trials of PLX-PAD in CLI

In 2009, Pluristem initiated two Phase 1 open label, dose-escalation studies, one in the U.S. and one in Germany, to evaluate the safety, tolerability, as well as efficacy of PLX-PAD in patients with CLI. Rutherford class 4-5 CLI patients that are not candidates for re-vascularization (no-option patients) were eligible for the trials. The German trial enrolled 15 patients, and three doses were tested: low dose ($175x10^6$ cells), intermediate dose ($315x10^6$ cells), and high dose ($595x10^6$ cells). PLX-PAD cells were injected in 50 sites intramuscularly as a one-time administration. Patients will be followed up for three months for safety, adverse events, and immunological reaction, as well as 24 months for tumorigenesis. The U.S. trial enrolled 12 patients and only tested the intermediate dose ($315x10^6$ cells) and high dose ($595x10^6$ cells). The intermediate dose was a single 30-site administration, and the high dose was administrated twice with 30-site injections each and the two administrations were separated by two weeks. Patients will be followed for three months for safety, adverse events, and immunological reaction, as well as for 12 months for delayed adverse events.

The Phase 1 trials enrolled a total of 27 patients (3 low dose, 12 intermediate dose, and 12 high dose). **It is worth noting that PLX cells from different donors were tested (seven placentas used), and the study tested different distributions (50 injection sites in the German trial and 30 injection sites in the U.S. trial). In addition, the study also tested different dosing regimens: one time injection vs. two administrations separated by two weeks. In the U.S. trial, 5 patients received a second PLX treatment from the same placental cells used in the first dose.**

In September 2010, Pluristem reported data from 21 patients who completed the three-month follow-up period. **The results showed that PLX-PAD cells can be administrated safely as an "off-the-shelf" product without need for matching between donor and patient. Efficacy assessment demonstrated that treatment with PLX-PAD cells significantly improved blood flow, pain score, and quality of life. It also appears that higher distribution of the cells and two separate treatments may have improved efficacy. Updated data from all 27 patients are expected to be reported in April 2011.**

Safety results: PLX-PAD cells may be safely injected, with no significant unfavorable effects occurred due to PLX-PAD. None of the patients developed an anti-HLA antibody response and no specific anti-PLX HLA class-I or class-II antibodies were detected in the patients tested, even for the patients treated twice with the PLX cells derived from the same placenta. There was one major amputation in the high-dose group shortly after early administration of PLX-PAD cells, representing 4.7% of all patients treated in this study. An increase in anti-inflammatory and angiogenic proteins were detected post-dosing.

Efficacy results: ABI improvement was achieved in 13 patients (62%), and 11 patients received the intermediate dose showed a statistically significant improvement from baseline (P=0.033). 13 patients (62%) demonstrated an **improvement in the Transcutaneous Oxygen Pressure (TcPO2)**, a measure of tissue oxygenation, and the improvement was statistically significant in the European study where the distribution of injections was higher (P=0.05). **Quality of Life** (QoL) was statistically significantly improved across all dose groups (81%) (P<0.001). **Pain score (VAS)** was statistically significantly reduced from baseline in all doses (p=0.009). Importantly, **only one major amputation occurred at 3 month for the 21 patients (4.7%), compared favorably to the results for the control group in other recently completed clinical trials (12~24%).**

Planned Phase 2/3 Trial in CLI

Pluristem is expected to initiate a multinational, randomized, double blind, placebo controlled Phase 2/3 study in CLI in 4Q11. The company has completed a parallel scientific advisory process with both the FDA and EMA, and the trial will be conducted under a joint FDA-EMA protocol. The company believes the trial may be a used for registration, supported by a Phase 2 trial in intermittent claudication.

The Phase 2/3 trial is expected to enroll 450 patients with Fontaine class III-IV, or Rutherford category 4-5 PAD patients. Patients will be randomized 1:1 to receive either PLX-PAD or placebo via multi-intramuscular injections to the affected leg. Each patient will receive two treatments, one at day 0 and one at day 120. PLX-cells will be injected intramuscularly to 30 sites, with 300 million cells for each treatment. **The primary endpoint is amputation-free survival (major amputation or death) rate at 12 months from initiation of the treatment.** The trial is 90% powered to show a 50% reduction, or 80% powered to show a 35% reduction in amputation free survival rate. In addition, an interim analysis is also planned after reaching about 80 events, with a potential to stop the trial early due to futility or significant efficacy. **We expect 18 months for trial enrollment and 12-month follow-up, with interim data expected in 2013 and final data expected in late 2014/early 2015.**

However, there are some inherent risks in the Phase 2/3 trial:

1) The primary endpoint of the proposed Phase 2/3 trial is amputation-free survival at 12 months, an outcome that has been studied at only 3 months to date in the Phase 1 trial. No other information is available on other ischemic-related events such as wound healing and incidence of gangrene.

2) Variability between patients and sites may potentially skew the results. CLI patients represent a very heterogeneous population. The decision to amputate involves many factors that may potentially vary between patients, sites, and physicians.

3) The current data and power calculations are based on 21 patients. The power assumptions may be aggressive or incomplete due to the modest amount of data available to date. An interim analysis with assessment of appropriate sample size is planned.

4) The amputation free survival outcome, judged to be the gold standard by the FDA concerning CLI trials, has historically been a tough one to intervene and improve upon.

Planned Phase 2 Trial in IC

Pluristem is expected to initiate a double blind, randomized, placebo controlled Phase 2 study in patients with intermittent claudication (IC) in 3Q11, under the U.S. FDA and the Paul Ehrlich Institute (PEI), the German competent authority in the EU. The trial is expected to enroll 135 patients with IC, randomized 1:1:1 to each of three arms: placebo control, low dose PLX-PAD (150 million cells), high dose PLX-PAD (300 million cells). Each patient will receive two treatments, one at day 0 and one at day 120. **The primary endpoint is percentage of patients with > 50% improvement in 6-minute walking distance at 12 months as compared to baseline.** This trial targets patients with Fontaine class IIb or Rutherford class 2 and 3 PAD and is intended to support CLI registration. Pluristem expects to take measures to reduce patient variability: 1) three treadmill tests will be run for each patient, and only patients with at least two tests falling in a pre-specified standard deviation will be enrolled; and 2) only patients with baseline 6-minute walking distance around 500 meters will be enrolled. The company expects a 50% improvement over placebo. **We expect the timeline to include 6 months of enrollment and 12 months of follow-up with data expected in 2013.**

Planned Phase 2/3 in Buerger's Disease

Buerger's disease is a rare disease, characterized by inflammation and clotting of the small arteries and veins in the hands and feet. **Buerger's disease affects ~12 persons per 100,000 in North America, and is more common in the Middle East and Far East.** The main symptom of Buerger's disease is pain at rest or with exercise. In many cases, ulcerations and gangrene may also occur that eventually may lead to amputation of the affected extremity.

Pluristem has submitted an orphan drug application for PLX-PAD for the treatment of Buerger's disease and plans to initiate a Phase 2/3 pivotal trial in 4Q11. Since amputation is not a common outcome in Buerger's disease, the company proposed pain reduction and improvement in walking distance as the primary endpoint for the trial.

Competitive Clinical Programs in CLI

As described above, the only potential curative treatment for limb salvage in CLI patients is revascularization. However, the current available revascularization approaches, such as open bypass surgery and endovascularization, may not be suitable for every patient, leaving amputation the only option for the patients ineligible for revascularization. The challenges in developing new alternative treatments for CLI is highlighted by the recent high-profile failure of the large RCT Phase 3 TAMARIS trial conducted by sanofi-aventis to evaluate FGF gene therapy vs. placebo in improving amputation free survival. While the FGF gene-encoded plasmid had demonstrated significant improvement in amputation free survival at 12 months in a RCT Phase 2 trial (14% for treatment group vs. 29% for placebo group), the Phase 3 trial failed to meet its primary endpoint of amputation free survival at 12 months (37% for treatment group vs. 33% for placebo group). Regenerative medicine approached have produced encouraging results in early-stage clinical trials, including autologous stem cells derived from bone marrow, adipose tissue or peripheral blood as well as allogeneic stem cells derived from placentas. Currently, there are approximately 40 Phase 2 clinical trials and 10 Phase 3 clinical trials ongoing for the treatment of CLI, with most clinical trials focusing on stimulating angiogenesis.

Figure 9: Recent Completed, Ongoing, and Planned Phase 3 trials in CLI

Sponsor	Treatment	Phase	Patient Population	Outcome	comments
Sanofi-Aventis	XRP0038/NV1FGF (FGF encoding plasmid) Vs. Placebo	Phase 3 (TAMARIS)	Unsuitable for standard revascularization	Primary: time to major amputation of the treated leg or death from any cause over 12 months Secondary: all amputations, death, ulcer healing, pain relief, functional status	n=525 Initiated November 2007; Completed 3Q10, failed to show amputation free survival rate difference
Mitsubishi Tanabe Pharma Corp	Ecraprost in lipid emulsion Vs. Placebo	Phase 3	Scheduled to receive a revascularization procedure as part of standard care	Primary: major amputation and death within 6 months after treatment Secondary: rate of major amputation, critical cardiovascular events, graft patency of index operations, complete ulcer healing, pain at rest	n=280 Initiated August 2001; Study was terminated.
Franziskus-Krankenhaus	Autologous Bone Marrow Cell Concentrate vs. Saline injection	Phase 2/3 (BONMOT)	No option for revascularization	Primary: major amputation of the index limb or persisting, unchanged CLI at 3 months Secondary: wound healing, pain and analgesics use, Rutherford grade and stage, walking distance, QoL, survival without amputation, rate and extent of minor amputation	n=90 initiated April 2007; Completed March 2010
Harvest Technologies	Bone Marrow Aspirate Concentrate Vs. Placebo	Phase 3	No reasonable open surgical or endovascular revascularization	Primary: amputation free survival at six month Secondary: Change in Rutherford classification, pain	n=210 Initiated January 2011; Expected to complete June 2014
CHU de Reims	Bone Marrow aspirate Vs. Placebo saline injection	Phase 3	No possible surgical treatment	Primary: major amputation rate and mortality at 6 months Secondary: Clinical symptoms and hemodynamic parameters	n=110 Initiated March 2009; Expected to complete August 2011
Leiden University Medical Center	Bone Marrow Derived Mononuclear Cells Vs. Placebo	Phase 2/3	Ineligible for angioplasty or bypass procedures	Primary: limb salvage/wound healing at 6 months; pain free walking distance Secondary: QoL (RAND-36), pain scores, transcutaneous oxygen pressure (TcO2), ABI artery scores	n=108 Initiated October 2007; Completed September 2010
Netherlands Society for Interventional Radiology	PTA with placement of paclitaxel-eluting stent Vs. PTA	Phase 2/3	Fontaine stage III and IV or Rutherford category 4, 5 or 6	Primary: primary patency defined as <50% loss of luminal diameter at the treated site at 6 months Secondary: primary patency at 3,6,12 months, clinical evaluation of the treated ischemic leg, major or minor amputation	n=140 Initiated August 2007; Expected to complete November 2013
Clinical Centre of Serbia with University of California, LA	Distal venous arterialisation vs. Aspirin	Phase 2/3	Absence of any possibility for direct revascularization, sufficient deep venous system and usable great saphenous vein as a graft for bypass	Primary: limb salvage over 1 year Secondary: lactate level in the blood of deep venous system	n=30 Initiated September 2009; Expected to complete July 2011
Aastrom	Bone marrow derived tissue repair cells (Ixmyelocel-T) vs. Placebo	Phase 3 (planned)	No treatment option patients with tissue loss	Primary: amputation free survival at 12 months	n=520 Expected to start 2Q11
Pluristem	PLX-PAD (placenta derived stromal cell) vs. placebo	Phase 2/3 (planned)	Fontaine class III-IV or Rutherford class 4-5	Primary: amputation free survival at 12 months	N=450 Expected to start 4Q11

Source: Clinicaltrials.gov, Needham & Company, LLC.

PLX in Other Indications

In addition to PAD, PLX cells may have broad applications in other ischemic, inflammatory, and degenerative diseases. Pluristem has conducted a variety of pre-clinical studies and generated early evidence of effect in multiple indications, including muscle injury, wound healing, neuropathic and inflammatory pain as well as ischemic stroke, inflammatory bowel disease, and multiple sclerosis.

PLX for Muscle Injury

In March 2011, Pluristem announced positive pre-clinical data demonstrating that PLX cells treatment following muscle injury resulted in significant improvement in the recovery of muscle function when compared to the control group. During the study in animal muscle injury models, PLX cells or placebo saline were injected directly into the traumatized muscles, either immediately or seven days after injury. Four weeks after administration, the regenerative capacity of the muscle was measured bilaterally by stimulating the sciatic nerve, which showed that PLX cells administration resulted in significant improvement in the recovery of the involved muscles. **We believe the results suggest that PLX cells may have application in different categories of muscle injury, including accidental injuries, such as sports injury, and intentional injuries, such as those incurred during surgery. Both these clinical scenarios have a high incidence in both the U.S. and EU.**

Encouraged by the pre-clinical findings, Pluristem has started discussion with the Paul Ehrlich Institute (PEI) of Germany regarding a clinical development plan for the usage of PLX cells as an adjuvant therapy for the recovery of muscle function following hip replacement surgery. In addition, the company plans to discuss with the FDA regarding a clinical development plan for PLX cells for the treatment of sports injury, including hamstring injury and tendon/ligament tears. **Pluristem expects to initiate an EU Phase 1/2 study in patients with hip replacement, and a U.S. Phase 1/2 study in patients with sports injury in 3Q11.** Two different doses of PLX cells will be evaluated: low dose of ~150 million cells and high dose of ~300 million cells. **The trial will follow-up the patients for three months, and data are expected in 1H12.**

PLX for Wound Healing

In March 2011, Pluristem formed a partnership with the New York University Medical Center to conduct pre-clinical studies to evaluate PLX cells for the treatment of diabetic foot ulcers (DFU). Planned studies will include an in vitro and a series of animal models to evaluate the role of PLX in healing DFU, with a potential to bridge the treatment of DFU in human. PLX cells will be injected around and below wound bed without using a scaffold. It is estimated that 20 million U.S. people have diabetes, of which 12% may develop DFU. **We believe that PLX cells may have potential in treating DFU by stimulating angiogenesis and promoting tissue regeneration. The company plans to initiate a Phase 2 study in 2012, if the preclinical data are encouraging.**

PLX for Neuropathic Pain

In August 2010, Pluristem announced results from two separate pre-clinical studies, demonstrating that PLX cells may be effective in treating both neuropathic and inflammatory nerve pain. The studies used two different animal models, including neuropathic pain models induced by ligation of the sciatic nerve and inflammatory model pain induced by the injection of complete Freund's adjuvant into the animal's footpads. **PLX cells treatment significantly reduced the sensitivity to the thermal and mechanical stimuli in both models in a dose dependent manner.** Pluristem is planning to move forward to clinical study of PLX for the treatment of neuropathic pain arising from a variety of reasons, such as diabetes and chemotherapy. **In addition, PLX may have potential treatment effect for CNS diseases.** In an animal model with multiple sclerosis, PLX cells were given intravenously. A significant reduction in the experimental autoimmune encephalitis (EAE) score was achieved for the animals treated with PLX cells as compared to controls. In an animal ischemic stroke model, intravenously injected PLX cells resulted in statistically significant improvement in functional endpoints of beam walking and neurological severity score as well as in anatomical endpoint of reduction in infarct size.

UPCOMING EXPECTED MILESTONES

- ✓ Received issuance of U.S. patent covering the 3D cell expansion (Oct. 2005)
- ✓ Initiated a Phase 1 trial of PLX-PAD in CLI in Germany (July 2009)
- ✓ Initiated a Phase 1 trial of PLX-PAD in CLI in the U.S. (September 2009)
- ✓ Reported preclinical data from studies of PLX in neuropathic and inflammatory pain model (August 2010)
- ✓ Reported three-month data from 21of 27 patients in the Phase 1 trials of PLX-PAD in CLI (September 2010)
- ✓ Completed a scientific process with the EMA and FDA regarding a Phase 2/3 trial in CLI (January 2011)
- ✓ Reported positive preclinical data from muscle injury study (March 2011)
- ✓ Entered into collaboration with NYU Medical Center to evaluate PLX in diabetic foot ulcers (March 2011)
- Report updated data from Phase 1 trials of PLX-PAD in CLI (2Q11)
- Initiate a Phase 2 trial of PLX-PAD in intermittent claudication (3Q11)
- Initiate Phase 2 trials of PLX in muscle injuries in both the EU and U.S. (3Q11)
- Initiate a Phase 2/3 trial of PLX-PAD in Buerger's disease (4Q11)
- Initiate a Phase 2/3 trial of PLX-PAD in CLI patients (4Q11)

PLURISTEM MANAGEMENT TEAM

A qualified management team leads Pluristem Therapeutics that includes experience in biopharma, biotech, academia, and finance.

Zami Aberman, Chairman & CEO, **joined Pluristem in September 2005** and changed the company's strategy toward cellular therapeutics. Mr. Aberman has 20 years of experience in marketing and management in the high technology industry. He has served as chairman of Rose Hitech Ltd. (investments), chairman of VLScom Ltd. (VoIP), and director of Ori Software Ltd. (data management). In 1992, Mr. Aberman was awarded the Rothschild Prize for excellence in his field from the President of the State of Israel. Mr. Aberman holds a B.Sc. in Mechanical Engineering from Ben Gurion University in Israel.

Yaky Yanay, VP Finance & CFO, joined Pluristem in 2006. Mr. Yanay was the CFO of Elbit Vision System Ltd. (EVSNF.OB), a company engaged in automatic optical inspection. He has extensive experience in the financing and management of technology companies. Mr. Yanay began his financial career at Ernst &Young Israel in 1999, where he served as a manager of audit groups for the technology sector. Mr. Yanay holds a bachelor's degree with honor in business administration and accounting from the College of Management Studies in Rishon Le Zion, Israel and is a Certified Public Accountant in Israel.

William R. Prather RPh, MD, Senior VP Corporate Development, joined Pluristem in 2007. In 1992, Dr. Prather pursued a career in the financial industry where he has held Senior Healthcare research positions for a variety of investment banks. Dr. Prather co-founded Panacos, Inc. and has been on the Boards of Boston Biomedica Inc. (a public medical diagnostics company), PriMed (a private medical device company), MdBio (a Maryland healthcare venture firm), and sat on the Advisory Board of MDS Capital Management, (a Canadian venture firm). Dr. Prather received his BS in Pharmacy (1970) and medical degree (1973) from the University of Missouri. He practiced internal medicine in the Kansas City, MO and Vail, CO areas until leaving Internal Medicine in 1987-1989 to pursue a Fellowship in Geriatric Medicine at Harvard University.

Frida Grynspan, PhD, VP Research & Development, joined Pluristem in 2009. Prior to joining Pluristem, Dr. Grynspan served as VP of R&D of a pioneering cell therapy company in Israel. Before that, Dr. Grynspan served as Senior Scientist at Intelligene Ltd., a developer of molecular biology diagnostic and therapeutic tools, and as an instructor and biochemist at Harvard Medical School. Dr. Grynspan earned her Ph.D. in Chemistry/Biochemistry from the University of Illinois, Chicago and her post-doctoral degree from Harvard Medical School/McLean Hospital.

Chaya Mazouz, VP Clinical and Regulatory Affairs, joined Pluristem in 2008. Prior to joining Pluristem, Chaya Mazouz held the position of clinical operations director for Medgenics, a clinical-stage biopharmaceutical company involving gene therapy, where she engineered Phase I/II clinical studies. In previous positions, Ms. Mazouz led a multi-center Phase II study for Pharmos, a pharmaceutical company, and was CRA and Project Manager at IDgene, a startup company engaged in gene discovery. Ms. Chaya Mazouz received her BSc in Nursing and MA in Philosophy of Science from the Hebrew University in Jerusalem and is a registered Nurse.

Amit Avrahami, VP Operations and Production, brings with him 20 years of experience in Operations and Production management in various industries such as Pharmaceutical, Hi-Tech, Medical Devices and Bio-Tec. Prior to joining Pluristem, Mr. Avrahami was "Site Manager & Director of Operations" at Colbar Life Science, a Johnson & Johnson subsidiary, which develops and produces Purified Collagen products. Mr. Avrahami holds a Bachelor's Degree in Industrial Management from Shenkar College, Israel and a Master's in Business Administration from Heriot-Watt University, England.

FINANCIAL ANALYSIS

For the FY2Q11 ended December 31, 2010, R&D expenses increased 67% to $1,578,000, as compared to $947,000 for the same period in 2009, due primarily to the increase in research and development activity and the progress of the company's clinical studies, including hiring 8 new employees since December 2009. SG&A expenses for the quarter were $1,246,000, compared to $875,000MM for the same period in 2009, due primarily to increase in stock-based compensation. Net loss for the quarter was $2,821,000 or $(0.11) per share. Operating cash usage for the six months ended December 31, 2010 was ~$2.2M. **The company expects the operation cash usage for FY2011 to be ~$7MM, and expects ~$3MM grant from the Israeli government to offset the operation cash usage, with a net operating cash burn rate of ~$4MM for FY2011.**

In February 2011, the company completed a public offering of 12,650,000 units at $3.25 per unit, with net proceeds of ~$38MM. Each unit consists of one share of common stock and one warrant to purchase 0.4 share of common stock at $4.20 per share exercisable on August 1, 2011 and expiring on August 1, 2016. exercisable at any time on or after the date of issuance until the fifth anniversary of the date of issuance. The company currently has ~41.6MM shares of common stock outstanding and 16.8MM warrants, with fully diluted shares of ~62.9MM.

The company ended 2010 with ~$4.7MM in cash and cash equivalents. As of March 31, 2011, the company had pro forma cash of ~$45MM, including ~$38MM net proceeds from the sale of common stocks and warrants in February 2011. Pluristem estimates that it may cost ~$15MM to conduct the pivotal Phase 2/3 trial in CLI, ~$5M to conduct the Phase 2 trial in IC, and ~$1.5MM to conduct the Phase 2/3 trial Buerger's disease. **With an expected net cash burn of ~$4MM for FY2011, we believe the company has sufficient cash to support operations and clinical programs through 2013.**

VALUATION ANALYSIS

We are initiating coverage of Pluristem Therapeutics with a Buy rating and a 12-month price target of $5. We derived our price target for Pluristem based on valuation of comparable companies. While we believe the target indications may have multi-billion-dollar market potential, we believe it is premature to project revenues or earnings for the company at this stage, as the only data available is from Phase 1 trials, and there is substantial uncertainty regarding the clinical trials, regulatory requirement, as well as potential issues surrounding scale-up of manufacturing and reimbursement. We believe a valuation model based on comparable companies is more appropriate than a revenue or EPS model. We chose our comparable companies for Pluristem based on: 1) compounds already in or soon to enter Phase 3 development; 2) encouraging Phase 1/2 results; 3) unmet medical need; and 4) a technology platform that can be leveraged for further product development. These companies included: ArQule Inc. (ARQL, BUY), Athersys (ATHX, NR), Celldex (CLDX, BUY), Cytori (CYTX, NR), Sangoma (SGMO, NR), Stem Cell (STEM, NR), and Vical (VICL, NR).

We believe Pluristem stock is trading at a substantial discount relative to its peers. In the near term, we believe the trial initiations and data updates from the ongoing clinical trials may drive the stock higher. In the long term, we believe the results from the Phase 2 trial in IC, Phase 2/3 trial in Buerger's disease, and Phase 2/3 trial in CLI, as well as the PLX technology platform will drive the long-term growth of the company.

INVESTMENT RISKS

Developmental Risk: While the preclinical data indicate that PLX cells may be effective in multiple indications, the only safety and efficacy data in human are from Phase 1 trials. The company plans for multiple trials in the PAD indication, which may provide sufficient information for registration. However, there is high uncertainty that the outcome may be positive. Power assumptions for the proposed trials appear to be aggressive as well. In addition, CLI is very heterogeneous, and variations may bias the results. Development in other indications is still early, and more proof of concept data may be needed for further development.

Regulatory Risk: FDA approval is dependent on the final data collection and its interpretation. No stem cell based therapy has been approved to date. The regulatory process may be more difficult than small molecular or biologics that have established registration pathway. A joint FDA-EMA registration pathway is being planned.

Commercialization/Marketing Risk: FDA approval does not guarantee clinical adoption. Cell-based therapy is novel for physicians, and extensive training may be needed. Pluristem does not have internal sales or marketing capability and may need to enter into an alliance with third parties for commercialization. Furthermore, since cardiovascular treatments are rapidly changing, competition may hinder regulatory approval and use in clinical practice.

Manufacturing Risk: PluriX 3D bioreactor is a highly scalable, and the company has successfully scaled up from 1 liter bioreactor to 5 liter bioreactor. The company may need to further scale up manufacturing for commercialization. It is critical to ensure the consistency of production of cells after scale up to commercial production. Failure to produce PLX batches that meet specifications could affect the company's ability to complete clinical trials or commercialize the drug.

Financial Risk: Pluristem ended 2010 with ~$4.7MM in cash and cash equivalents. As of March 31, 2011, the company had pro forma cash of ~$45MM, including ~$38MM net proceeds from the sale of common stocks and warrants in February 2011. The Company estimates that it may cost ~$15MM to conduct the pivotal Phase 2/3 trial in CLI, ~$5M to conduct the Phase 2 trial in IC, and ~$1.5MM to conduct the Phase 2/3 trial Buerger's disease. **With an expected net cash burn of ~$4MM for FY2011, we believe Pluristem has sufficient cash to support operations and clinical programs through 2013.**

Intellectual Property Risk: Pluristem currently has 3 issued U.S. patents and 11 non-U.S. patents, which will expire in 2020, without consideration of potential extension under Hatch-Waxman Act. The issued patents cover the use of 3D cell culture for maintaining and expanding adherent stromal cells, directional change of the cells during 3D culturing, and therapeutic uses of adherent stromal cells. In addition, the patents also protect the concept and mechanism of action of PluriX bioreactor, including mimicking the bone marrow environment and expansion of cells without using exogenous growth factors. Due to the requirement for unique expertise and novelty of stem cell therapy technology, we believe the company faces very low risk of competition from generics.

Pluristem Therapeutics, Inc.

Balance Sheet ($000s)

Fiscal Year Ends June 30	1Q08	2Q08	3Q08	4Q08	1Q09	2Q09	3Q09	4Q09	1Q10	2Q10	3Q10	4Q10	1Q11	2Q11
Current assets														
Cash and cash equivalents	562	462	1,764	323	1,978	2,193	1,724	2,339	2,141	1,383	1,119	1,583	1,127	4,739
Short-term investments	3,693	3,419	1,571	1,185			240			2,500	898	913	517	
Prepaid expenses	253	251	206	350	393	183	109	100	129	72	40	41	80	56
Accounts receivable from the Office of the Chief Scientist	733	519	113	119	117	368	72	383	207	21	226	706	318	361
Other accounts receivable	429	401	205	130	173	145	237	113	120	81	109	362	71	375
Total current assets	**5,670**	**5,052**	**3,859**	**2,107**	**2,661**	**2,889**	**2,382**	**2,935**	**2,597**	**4,057**	**2,392**	**3,605**	**2,113**	**5,531**
Long-term deposits	124	118	199	201	178	168	169	171	171	178	180	168	169	176
Severance pay fund	102	123	108	127	148	149	124	154	186	241	270	294	327	359
Property and equipment, net	611	979	1,111	1,149	1,189	1,175	1,228	1,203	1,254	1,253	1,243	1,555	1,756	1,816
Other long-term assets														
Total Assets	**6,507**	**6,272**	**5,277**	**3,584**	**4,176**	**4,381**	**3,903**	**4,463**	**4,208**	**5,729**	**4,085**	**5,622**	**4,365**	**7,882**
Current liabilities														
Trade payable	532	454	616	622	403	525	356	487	489	596	632	791	673	926
Accrued expense	106	95	100	154	193	78	32	81	77	83	62	118	157	85
Other accounts payable	177	211	266	296	257	243	264	272	323	378	431	372	400	468
Total current liabilities	**815**	**760**	**982**	**1,072**	**853**	**846**	**652**	**840**	**889**	**1,057**	**1,125**	**1,281**	**1,230**	**1,479**
Accrued severance pay	120	147	130	147	163	174	170	206	248	288	332	360	403	420
Other non-current liabilities	36	35	36	36	33	28	23	23	-	-				
Total Liabilities	**971**	**942**	**1,148**	**1,255**	**1,049**	**1,048**	**845**	**1,069**	**1,137**	**1,345**	**1,457**	**1,641**	**1,633**	**1,899**
Shareholders' equity														
Commom stock	12													
Additional paid-in capital	23,406	25,870	27,321	28,345	31,385	32,424	34,143	36,046	37,340	40,484	40,991	44,086	44,526	50,598
Accumulated deficit	(17,882)	(20,540)	(23,192)	(26,016)	(28,258)	(29,091)	(31,085)	(32,652)	(34,269)	(36,100)	(38,363)	(40,105)	(41,794)	(44,615)
Total shareholders equity	**5,536**	**5,330**	**4,129**	**2,329**	**3,127**	**3,333**	**3,058**	**3,394**	**3,071**	**4,384**	**2,628**	**3,981**	**2,732**	**5,983**
Total liabilities and shareholders equity	**6,507**	**6,272**	**5,277**	**3,584**	**4,176**	**4,381**	**3,903**	**4,463**	**4,208**	**5,729**	**4,085**	**5,622**	**4,365**	**7,882**

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Pluristem Therapeutics, Inc.

Income Statement ($000s except per share data)

Fiscal Year Ends June 30	FY07A	FY08A	FY09A	1Q10A	2Q10A	3Q10A	4Q10A	FY10A	1Q11A	2Q11A	1Q11E	2Q11E	FY11E	FY12E
Product sales and rentals													-	
Grants				-	-			-					-	
Total Revenues	**-**	**-**	**-**	**-**	**-**		**-**	**-**	**-**	**-**	**-**	**-**	**-**	
COGS														
Operating Expenses														
Research & Development, net	2,549	4,393	3,141	867	947	1,490	997	4,301	998	1,578	950	989	4,515	12,786
General & Administrative	3,726	6,036	3,417	770	875	768	725	3,138	756	1,246	1,028	1,146	4,176	6,482
Know how write off	1,963													
Total Operating Expenses	**8,238**	**10,429**	**6,558**	**1,637**	**1,822**	**2,258**	**1,722**	**7,439**	**1,754**	**2,824**	**1,978**	**2,135**	**8,691**	**19,268**
Operations Income (loss)	**(8,238)**	**(10,429)**	**(6,558)**	**(1,637)**	**(1,822)**	**(2,258)**	**(1,722)**	**(7,439)**	**(1,754)**	**(2,824)**	**(1,978)**	**(2,135)**	**(8,691)**	**(19,268)**
Interest expense													-	
Interest income														
Other income (expense)														
Total other Income (expense)	**(191)**	**(69)**	**(78)**	**20**	**(9)**	**(5)**	**(20)**	**(14)**	**65**	**3**	**15**	**24**	**107**	**75**
Net Income (Loss) before Income Taxes	**(8,429)**	**(10,498)**	**(6,636)**	**(1,617)**	**(1,831)**	**(2,263)**	**(1,742)**	**(7,453)**	**(1,689)**	**(2,821)**	**(1,963)**	**(2,111)**	**(8,584)**	**(19,193)**
Income Taxes (Benefits)				-			-							
Net Loss	**(8,429)**	**(10,498)**	**(6,636)**	**(1,617)**	**(1,831)**	**(2,263)**	**(1,742)**	**(7,453)**	**(1,689)**	**(2,821)**	**(1,963)**	**(2,111)**	**(8,584)**	**(19,193)**
EPS: Basic and Diluted	**$ (5.85)**	**$ (1.63)**	**$ (0.63)**	**$ (0.11)**	**$ (0.10)**	**$ (0.13)**	**$ (0.09)**	**(0.44)**	**(0.08)**	**(0.11)**	**(0.05)**	**(0.05)**	**(0.28)**	**(0.44)**
Basic and Diluted Weighted Avg. Shares Outstanding	1,442	6,422	10,602	14,523	17,449	18,003	19,489	17,004	21,012	24,897	36,457	41,856	31,056	43,568

Needham & Company, LLC
3/25/2011

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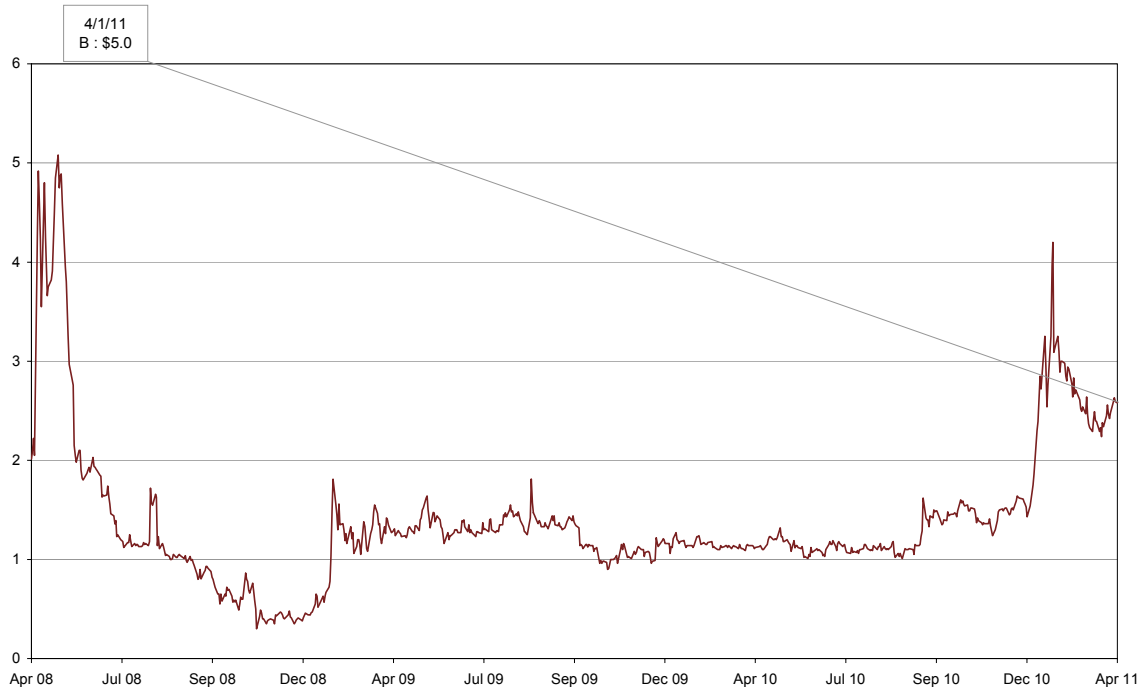
I, Bryan Huang, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject company (ies) and its (their) securities. I also certify that I have not been, am not, and will not be receiving direct or indirect compensation in exchange for expressing the specific recommendation(s) in this report.

Price, Rating, and Price Target History: Pluristem Therapeutics, Inc. (PSTI/NASDAQ) as of 4-1-11



Source: Factset (Prices) / Needham (ratings and target price)

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	% of companies under coverage with this rating	% for which investment banking services have been provided for in the past 12 months
Strong Buy	8	17
Buy	62	15
Hold	28	5
Under Perform	<1	0
Rating Suspended	2	0
Restricted	0	0
Under Review	0	0

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